STATEMENT

OF

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BEFORE THE

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Introduction

Chairman Gregg and members of Committee, I am honored to be with you today to discuss a key element of the President's health care agenda-- health information technology (IT). The President and I are committed to promote health information technology and we believe that it will yield lower health care costs, reduction in medical errors, and enhanced quality of care. Today, I will provide a brief overview of our Department's health information strategy and the activities underway at this time.

Setting the Context

When President Bush asked me to become Secretary of the Department of Health and Human Services (HHS), he charged me with helping Americans live longer, healthier lives and with doing so in a way that will maintain our economic health as a nation. While the U.S. offers world-class health care, it also spends nearly 16% of its GDP on health care or \$1.8 trillion. In 1960, 5.1% of our GDP was spent on health care. Estimates are that it could be close to 19% of GDP by 2014. This is almost twice the average among European Union countries, with a growing portion attributable to Medicare spending.

While other industries like shipping, retail, and banking have successfully transformed the way they do business through the use of information technology, the health care industry's use of information technology has lagged. Furthermore, the productivity of the health care sector in the U.S. has failed to keep pace with its spending.

While much of this spending is unavoidable, the current system is saturated with inefficiency. In fact, economists believe that up to a third of health care spending – more than half a trillion dollars a year – is wasted because of poor or redundant care or other problems.

And it's not just a matter of dollars – it's a matter of human lives. The Institute of Medicine has estimated that medical errors are responsible for the deaths of 44,000 to 98,000 Americans every year in hospitals. The information necessary for clinicians to treat their patients is often missing

at the point of care. Our nation is facing an economic and humanitarian imperative in health care—we must become more efficient or face losing our economic prosperity and precious human lives.

Nothing short of transformation of our health care system will do. What are the big gears of health care transformation? I think there are three.

Perhaps the biggest gear is a change in the way we think about health care. When I was Administrator of EPA, I learned that it is much easier and less costly to prevent pollution than to clean it up. The same principle can be applied to health care. We need to become a society who thinks of staying healthy rather than simply being treated after we're sick. That is the reason the President fought so hard for a prescription drug benefit and other preventive benefits for seniors. That is the reason he is pressing hard for progress on obesity and emphasizing the importance of exercise and eating healthy. These lifestyle changes help prevent the onset of chronic diseases, such as Type 2 diabetes and heart disease. An increasing amount of our total health care costs as a nation are from preventable and manageable chronic diseases.

The second big gear is realigning health care incentives. The incentives in our health care system are just wrong - wrong for providers, wrong for payers, wrong for patients. Providers get paid on the basis of the quantity of the care they provide, not the quality of outcomes. Until this changes, we cannot transform health care. I am determined to see pay-for-performance become part of the way we compensate health care providers. We are already starting to implement these changes in the Medicare program. For example, the Medicare Care Management Performance

Demonstration (MMA section 649) is a three-year pay-for-performance demonstration involving physicians to promote the adoption and use of health information technology to improve the quality of patient care for chronically ill Medicare patients. Doctors who meet or exceed performance standards established by CMS in clinical delivery systems and patient outcomes will receive bonus payments for managing the care of eligible Medicare beneficiaries. This demonstration, which is currently under development, is focused on small and medium-sized physician practices. It will be implemented in four states: Arkansas, California, Massachusetts, and Utah, with the support of the Quality Improvement Organizations in those states.

Likewise, current consumer incentives are counterproductive. If a person is sent into a store and told they can buy all they want and the price doesn't matter, the outcome is predictable. Too often, that's how our health care system works. Transformation will not occur until we change these incentives. That is why the President feels so passionately about tax-free health savings accounts [HSAs]. Owners of HSAs have an incentive to become more cost-conscious consumers of health care.

The third big gear is the widespread adoption of interoperable health information technology. Health information technology is a tool which holds much promise for improving the quality of care Americans receive by preventing medical errors, providing clinicians with better clinical decision-making tools, sharing information with other clinicians involved with the treatment of their patients, tracking health outcomes and coordinating public health activities. While improving the quality of care Americans receive is important, health information technology can also lead to cost savings, through better coordination of care, information sharing, reducing redundancies, and preventing errors.

Last year, the President made the use of health information technology a key principle of his health care agenda. On April 27, 2004, the President signed Executive Order 13335 (EO) announcing his commitment to the promotion of health information technology to lower costs, reduce medical errors, improve quality of care, and provide better information for patients and physicians. In particular, the President called for widespread adoption of interoperable electronic health records (EHRs) within 10 years so that health information will follow patients throughout their care in a seamless and secure manner. This means that their medical information is available to the right people at the right time, while remaining protected and secure. The President has tasked HHS with making this vision a reality by 2014. The goal can be met, but there are major challenges to be faced, and the path forward requires a concentrated nationwide effort to achieve widespread adoption of interoperable EHRs.

This Administration's commitment is clear. HHS will spend \$85 million on health IT in FY05, and President Bush has requested another \$125 million for health IT in FY06. This commitment

will support the foundational work of the Office of the National Coordinator for Health Information Technology and the Agency for Healthcare Research and Quality that is required to achieve the President's goals in 10 years.

Key Challenges

There has been great progress in the past year, and I am optimistic about the future of health IT. However, there is much more to be done, and we have to work to address real issues and barriers that will halt the remarkable progress that is being made.

The Adoption Gap:

The first challenge is an adoption gap. Although low EHR adoption overall is a concern, there is a bigger concern with the varying rates of EHR adoption. Some clinicians adopt EHRs more readily than others – creating an adoption gap based, in large part, on the size of practice. This could prevent market forces and competition from improving healthcare. According to a study by the Commonwealth Fund, 57% of large group practices of 50 or more physicians are using an EHR, but only 13% of solo practitioners are doing so. Larger practices have more resources, more ability to acquire information technology and more capacity to implement technology well. These early adopters should be commended for their leadership, and they should not be faulted for their inventiveness. But, we need to develop solutions that assist EHR adoption up and down the spectrum of care delivery organizations. Effective adoption of health IT can preserve what is unique and valuable about small practices, where approximately 70 percent of physicians practice. We are particularly focused on the needs of these clinicians in their IT programs.

Interoperability:

A second challenge is achieving interoperability and minimizing the limitations of proprietary data that cannot be exchanged between different systems. The U.S. health care system is complex, fragmented, and uses multiple standards for the use of technology. It is analogous to the railroad system that existed in America in the 1850's. Several railroad companies began laying tracks and competing for business, but the rail gauges (or, width of the tracks) varied, so that most trains couldn't switch from one network to another. The continent had multiple,

incompatible networks instead of one interoperable network. We solved our rail problem long ago, but now we face a similar hurdle with health IT. I have seen this first hand through a recent visit to a major U.S. city where an academic medical center, county hospital, and a children's hospital existed within blocks of each other. Each had made substantial investments in health IT, but each invested in different IT systems from different vendors. In the end, these hospitals have a common geographical service area and share many physicians on their medical staffs, but the information systems at these hospitals were incompatible with each other. This is a story repeated across the U.S. The rail gauges don't line up. We cannot let this continue in our health care system. As a result, patient information exchange is limited at best; it cannot be transferred electronically from one setting to another. If we are not able to address the challenge of interoperability, the health IT systems today will further set in concrete the silos of information existing today on paper. More importantly, the chance for true transformation of our healthcare system will have been lost – along with many promising potential benefits.

The spirit of the transcontinental railroad is alive in health IT. People want to build it, and there is a sense of urgency. We are spending lots of time building elaborate railcars, but not enough in lining up the tracks. It is the power of a competitive free market that will make this happen, and we are blessed to have innovators and entrepreneurs that are capable of making miracles happen. But the promise of health IT will only be realized when all this power is channeled into creating a standardized system that is open, adaptable, interoperable, and predictable.

HHS is taking advantage of the current low adoption rate for EHRs, and putting the goal of interoperability forward first. When interoperability is in place, EHR adoption will follow.

The Path Forward

I'm persuaded there are only three possible ways that interoperability will emerge.

• The federal government can choose a standard and mandate it. That sounds easy, but it almost never works because it ignores a lot of good ideas in the private sector, and people instinctively fight it.

- The second way is to let vendors fight it out. I call that method the "last vendor standing." It works for some things, but not railroads or national frameworks for health information interoperability. The inevitable result is multiple standards and incompatibility.
- The third method and the only real alternative is a guided collaboration. Let's face it: collaboration is hard, and private sector technology competitors are not hard wired to do it; but it's also absolutely indispensable, and it works.

It has become clear that the challenge of health IT interoperability is a compelling national problem and that it will require an extraordinary measure to achieve it. It requires a sustained effort that goes beyond a private effort—and, beyond a federal effort. This requires a nationwide effort, harnessing the best of every sector.

In an effort to channel this momentum and continue toward meeting the President's goal, I am forming a national collaboration to dramatically intensify the pace of progress in health information technology. On July 14, 2005 I published a notice in the Federal Register to create the American Health Information Community (the Community). This body will be tasked with helping the nation transition to electronic health records – including common standards and interoperability – in a smooth, market-led way. The President intends the Community to be the place where major government players and private sector interests unify behind a common framework achieving interoperability. The Community will be an open, transparent and inclusive collaboration involving the critical mass necessary to get things done.

The Community, which will be formed using the procedures of the Federal Advisory Committee Act, will provide input and recommendations to HHS on how to make health records digital and interoperable, while assuring the privacy and security of those records remain protected. The Community is being chartered for two years, with the option to renew for a duration of no more than five years. It is my intention that the Community be succeeded within five years by a private-sector health information community initiative that, among other things, would set additional needed standards, certify new health information technology, and provide long-term governance for health care transformation.

The Committee will not exceed 17 voting members, including the chairperson. It will consist of nine members from the public sector and eight members from the private sector. Public Sector members will be drawn from Department of Health and Human Services (including the Office of the Secretary, the Centers for Medicare and Medicaid Services, and the Public Health Service), Department of Veterans Affairs, Department of Defense, Department of Commerce, Department of the Treasury, Office of Personnel Management, and a State government. The private sector membership will be drawn from purchasers, third-party payers, hospitals, physicians, nurses, ancillary services (e.g., lab or pharmacy), consumer and privacy interests, and health information technology. This is of such importance to the transformation of health care in America that I have concluded that, as Secretary of Health and Human Services, I should serve as the Community's first chairman. Nominations for the Community are due August 5, 2005.

The Community will start by building on the vast amount of standardization already achieved inside and outside the healthcare industry. Specifically, the Community will:

- 1) Make recommendations on how to maintain appropriate and effective privacy and security protections.
- 2) Identify and make recommendations for prioritizing health information technology achievements that will provide immediate benefits to consumers of health care (e.g., drug safety, lab results, bio-terrorism surveillance, etc.).
- 3) Make recommendations regarding the ongoing harmonization of industry-wide health IT standards and a separate product certification and inspection process.
- 4) Make recommendations for a nationwide architecture that uses the Internet to share health information in a secure and timely manner.
- 5) Make recommendations on how the AHIC can be succeeded by a private-sector health information community initiative within five years. (The sunset of the AHIC, after no more than five years, will be written into the charter.)

Furthermore, I have also issued four requests for proposals (RFPs). The products of these contracts will, in part, serve as inputs for the AHIC's consideration. We expect to award

contracts for these RFPs in September 2005. Specifically, the RFPs will focus on four major areas:

- 1. Standards harmonization: Harmonization of standards is fundamental to the success of widespread interoperability. Today, we have many standards for information exchange, clinical vocabulary and coding, but we have not harmonized them. These variations may hinder interoperability and the widespread adoption of health IT. There are also gaps in standards. The contractor selected will be asked to develop, prototype, and evaluate a harmonization process for achieving a widely accepted and useful set of standards. These standards would be designed to enable and support widespread interoperability among health care software applications, particularly EHRs.
- 2. Compliance certification: There are more then 200 EHR products on the market today, but there are no criteria to evaluate product functionality and interoperability. The variability and lack of criteria limit physicians' and hospitals' ability to make informed buying decisions. Agreement on product capabilities and compatibilities would reduce the risk of poor IT investment by healthcare providers. The contractor selected will be asked to develop criteria for the functional requirements for health IT products, as well as the infrastructure components through which EHRs interoperate.
- 3. Nationwide Health Information Network (NHIN) Architecture: Today, there is no consensus regarding how to utilize the Internet infrastructure to support interoperable health information exchange. As a result, information is often fragmented and incomplete at the point of care. The contractors selected will develop models for an NHIN architecture that would maximize the use of existing resources, such as the Internet, to achieve widespread health care interoperability.
- 4. **Security and privacy:** Currently, privacy and security practices vary by state and health care organization and this variation poses a challenge to widespread health care information exchange. The contractor selected for this RFP will define workable mechanisms and policies to address these variations, while maintaining the levels of security and privacy that consumers expect.

Other Health IT Initiatives Underway

In addition to the Community and four RFPs, there is other significant work underway at the Department which I would like to mention. I would like to highlight two initiatives here.

E-Prescribing

Shortly after being appointed Secretary, I announced proposed regulations to establish a foundation set of standards to support electronic prescriptions for Medicare. E-prescribing can improve patient safety and reduce avoidable health care costs by reducing prescription errors due to hard-to-read physician handwriting and by automating the process for checking for drug interactions and allergies. E-prescribing can also help ensure patients and health professionals have the best and latest medical information at hand when they make important decisions about medicines, helping patients get the most benefits at the lowest cost. The electronic drug prescribing initiative will accelerate the nationwide adoption of e-prescribing in Medicare, which is expected to accelerate e-prescribing throughout the nation's health care system. The regulations implementing the Part D benefit under the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) provide that e-prescribing based on national standards be mandatory for drug plans participating in the new Medicare Part D program.

A critical piece in nationwide adoption of e-prescribing is the promulgation of the MMA mandated exception to the physician self-referral statute [the Stark provision] and the safe harbor to the anti-kickback statute, which would enable hospitals, group practices, Prescription Drug Plan sponsors and Medicare Advantage organizations to donate software to physicians and other providers for use in e-prescribing. We plan to issue proposed regulations for the physician self-referral exception and for the safe harbor to the anti-kickback statute very soon.

Efforts at the Agency for Health Research and Quality (AHRQ)

In FY 2004, AHRQ awarded 108 grants and contracts to advance the use of health IT across the nation. These awards will provide insight into how best to use health information technologies to improve patient safety by reducing medication errors; increasing the use of shared health information between providers, laboratories, pharmacies and patients; helping to insure safer patient transitions between health care settings, including hospitals, doctors' offices, and nursing homes; and reducing duplicative and unnecessary testing. Specifically, we awarded grants and contracts for three specific purposes:

- 1. Planning, implementation and research grants: The grants are to build the knowledge base for how to do health IT well, and to seed essential partnerships. The grants are for three years and were awarded to 38 different states, with a special focus on small and rural hospitals and communities. These programs are anticipated to have a positive impact on 40 million Americans.
- 2. Develop statewide and regional networks: Contracts were awarded for five years to five states who have taken a leadership role in advancing health IT (Colorado, Indiana, Rhode Island, Tennessee and Utah) to help them develop secure, statewide networks.
- 3. Encourage adoption of Health IT by sharing knowledge: This five-year contract was provided for the creation of the National Health Information Technology Resource Center to provide technical assistance and promote best practices to grantees and contractors to aid them in their Health IT adoption efforts. The Resource Center is also being made available to community health centers and rural health programs across the country.

Reflecting a commitment of \$139 million over five years, these awards were truly nationwide in scope. They spanned 43 states, with over half of the projects based in rural and small hospitals and clinics. In combination, these community-based health care institutions provide health care to more than 40 million Americans.

Conclusion

HHS will continue to lead the nation along the path toward interoperability as a convener and an early adopter. The path will be difficult, and it will be painful at times. But, with the right commitment and the right leadership, we will create a transformation in our healthcare delivery system that is meaningful and that is lasting. In doing so, we can transform our health care system so that we achieve fewer medical mistakes, lower costs, better care, and less hassle. We all agree transformation must take place; now let's all agree to work together to do it. Abraham Lincoln transformed transportation in America. George Bush is resolved to do the same thing for health care. And, I am committed to seeing the President's goal become reality.